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March 17, 2004

TO: FAAN Members

FROM: Anne Muñoz-Furlong

I am writing to ask for your help in tackling what may very well be one of the most important issues that FAAN has ever faced.

For years the FDA has protected food allergic individuals by recalling mislabeled food products. Often these recalls were initiated by a consumer complaint of a reaction or other information indicating the presence of an undeclared allergen in a product.

FAAN is aware of several instances, however, when the FDA has been informed that a food allergic individual has had an allergic reaction to a food, analytical testing has confirmed the presence of an undeclared allergen in the food, yet the FDA has refused to classify the incident as a recall. The FDA has told us that this is because the analytical test has not been validated and as such, could not be used as evidence in court.

We have been meeting with top-level FDA officials to discuss FAAN's concerns but have been unable to get the FDA to classify these incidents as recalls or to take action on these products.

Our concern for the safety of the millions of individuals with food allergy is growing. Products with undeclared allergens that have already triggered allergic reactions may remain on the market. It is time for FAAN members to come together and let the FDA and elected officials hear our voices on this issue.

FAAN believes a consumer complaint *alone* should be sufficient to generate an FDA investigation. When the FDA finds supporting evidence, such as an admission from the manufacturer of a processing error, records demonstrating the mistaken addition of an allergen to the food and/or analytical results identifying undeclared allergens, FAAN believes that it is *imperative* that the products be quickly removed from the marketplace to protect other individuals with food allergy. For years, the FDA operated under this system.

Recalls in the U.S. are voluntary; however, in our opinion, FDA's oversight and enforcement action is essential to assure that the manufacturers involved will do their best and will work quickly to remove any mislabeled product from the market. Without FDA action or enforcement, some companies won't be motivated to label accurately or to recall products when mistakes are discovered. This is a slippery slope that can potentially lead to more reactions, hospital visits, and deaths from reactions to mislabeled products.

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